FEB 2 3 2006

K053378

510(k) Summary

Loop-Recorder vitaphone 3100 Series

Submitter: TMS Telemedizinische Systeme GmbH
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Contact Person:
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Establishment Registration Number: 3005191294

Trade Name: Vitaphone 3100 Series

Common Name: Tele ECG System, Cardiac Event Recorder, Loop-Recorder

Classification Name: Telephone electrocardiograph transmitter and receiver (per 21 CFR Section 870.2920, Product Code: DXH)

1. Predicate Devices

Device Type	ER800	King of Hearts Express AF	SM100	PMP4 SelfCheck ECG
Manufacturer	Braemar Inc.	Instromedix	TMS Tele-medizinische Systeme GmbH	Card Guard Ltd.
510(K) Number	K042469	K020825	K050670	K042254

The subject device shares operating characteristics and features with the predicate devices.

The technical specification comparison reveals no substantial differerence between the 3100 Series device and the predicate devices and no differences which affect safety or efficacy.

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2. Intended Use

The 3100 Series device is single-channel looping cardiac event recorder for transmitting multiple ECG recordings via land-line or GSM telephony networks to a compatible ECG receiving system, such as „sensor mobile" REMOS ECG Receiving Software (510(k) K050670) or compatible standard acoustic ECG receivers.

The 3100 series device is intended for auto-triggered and patient activated event recordings (Bradycardia, Tachycardia and Atrial Fibrillation). It is battery driven and utilizes a loop-memory to capture ECG data with an adjustable pre- and post-event time.

3. Device Classification

The system is classified as Class II medical device (21 CFR 870.2920).

4. Substantial Equivalence

Through the data and information presented in this 510(k) submission TMS Telemedizinische System GmbH considers the 3100 Series device as substantially equivalent to the previously discussed predicate devices.

TMS Telemedizinische Systeme GmbH
Tilo Borchardt
Director Engineering

Signature: .....

Date: 2005-10-14

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2006

TMS Telemedizinische Systeme GmbH
c/o Mr. Jeffrey Rongero
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K053378
Trade Name: TMS Loop Recorder Vitaphone 3100 Series
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: February 8, 2006
Received: February 10, 2006

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Loop Recorder vitaphone 3100 series

Indications for Use:

Diagnostic evaluation of patients with asymptomatic and symptomatic disturbances of the cardiac rhythm such as:

- Dizziness
- Heart race
- Palpitations
- Syncopes of unknown cause

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053378